UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: March 14, 2006

SUBJECT: Permethrin: Review of Valent BioSciences Corporation's CARES Aggregate Submission entitled "Preliminary Evaluation of Potential Aggregate Human Health Risks Associated with Agricultural and Consumer Uses of Permethrin" (dated June 21, 2005). MRID 465785-01; DP Barcode 358432.

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Conclusions:

Valent BioSciences Corporation, Environmental Science Division (Valent) has submitted an aggregate assessment for permethrin conducted with CARES (Cumulative and Aggregate Risk Evaluation System), a software program which performs single chemical, aggregate, and cumulative (multichemical) exposure and risk assessments. In the submission, exposures through food, water, and residential pathways were assessed. The Health Effects Division (HED) has reviewed and evaluated the Valent permethrin submission with respect to the Environmental Protection Agency (EPA) and Office of Pesticide Programs (OPP) guidelines and standard operating procedures for submission of probabilistic assessments. HED's review

particularly focused on the residential pathways of exposure as these exposures were the main driver in HED's non-cancer deterministic aggregate assessment. Overall, HED finds the assessment submitted by Valent to have selected reasonable input parameters to estimate exposure to permethrin from the food and residential pathways. The assessment does not currently reflect the revised drinking water memo completed by the Environmental Fate and Effects Division (EFED) on January 17, 2006 (J. Melendez).

Detailed Analysis:

A. Overview

Valent BioSciences Corporation, Environmental Science Division (Valent) has submitted an aggregate assessment for permethrin conducted with CARES (Cumulative and Aggregate Risk Evaluation System). The submission, entitled "Preliminary Evaluation of Potential Aggregate Human Health Risks Associated with Agricultural and Consumer Uses of Permethrin" was dated June 21, 2005 and prepared by Infoscientific.com, Inc. for Valent. The Valent assessment evaluated the human health risks associated with current agricultural and consumer uses of products containing carbaryl through potential food, water, and non-dietary exposures to adults and children 1-2. Exposure and risk (MOE) estimates were provided at the 99.9th percentile for food alone, drinking water alone, residential uses alone, and the for the overall per capita aggregate. More specifically, the Valent assessment assessed the exposures through food primarily using pesticide residue data from the U.S. Department of Agriculture (USDA) Pesticide Data Program (PDP). Exposures through residential uses were based on reported uses in the 12 month REJV survey and included residential lawn uses, vegetable garden uses, outdoor wasp and hornet aerosol uses, indoor crack and crevice uses, termite treatments, pet care uses, outdoor and indoor fogger uses, indoor flying insect killer uses, impregnated materials (clothing), indoor carpet and room treatments, and public health uses (mosquito control).[1] Permethrin formulations which were assessed in the submission are aerosols, dusts, ready to use pet shampoos and pet spot-on treatments, liquid concentrates, granulars, and products impregnated with permethrin. Application methods included: aerosol cans, dust shaker cans, handwand/pump sprayers, total release aerosol foggers, truck mounted foggers, and RTU shampoo and spot-on packaging.

The Valent submission was conducted with CARES, v.2.0. The CARES program was developed by a consortia sponsored by Crop Life America, and is a software program through which single chemical discrete pathway assessments, single chemical multi-pathway aggregate risk assessments, or multi-chemical, multi-pathway cumulative assessments can be performed. Food, drinking water, and residential exposure pathways can all be considered. The dietary component of CARES provides, as a base output, the exposures and associated risks (MOEs) at a variety of user-selected percentiles. In addition, the program permits the user to conduct further in-depth analysis of such areas as contribution and sensitivity. The CARES program was reviewed by the FIFRA Scientific Advisory Panel on April 30/May 1, 2002 and the review material (including an older version of the manual, the Panel report, and a variety of technical appendices and http://www.epa.gov/oscpmont/sap/2002/april/cares.htm. A written copy of the Valent submission and background information on CARES can be obtained in the OPP docket.

As part of its submission, Valent used a variety of databases as sources of data for the CARES model. Selected sources are discussed briefly below:

Pesticide Data Program (PDP) Data: Data from the USDA's PDP program was used extensively by Valent in its permethrin CARES submission. The PDP program was implemented by USDA in 1991 to collect residue data on foods. The program covers a multitude of pesticides (including permethrin) on a wide variety of fresh and processed fruits and vegetables, whole milk, grains, and grain products. The samples (generally 5 lb composites) are collected by federal and state governmental personnel from warehouses and other central markets immediately prior to shipment to commercial (retail) establishment for purchase by the consumer. Thus, the sampling is done as close to the consumer as possible and measured pesticide residues are expected to closely reflect that to which the consumer is exposed. A total of 10 states participate in the PDP program and sampling is designed to be reflective of the entire U.S. population. OPP uses this as principal source of information for the risk assessments it conducts.

REJV (12 month version):. The Residential Exposure Joint Venture (REJV) is an industry task force that sponsored a homeowner pesticide use survey (hereafter referred to as the REJV survey) conducted between May 2001 and April 2002. There are several components to the REJV survey. The first component consists of a screener questionnaire of an NFO Worldgroup household panel - the survey research firm contracted by the REJV. In this screener survey, the respondents were asked several questions regarding pesticide use. For efficiency considerations, only "pesticide users" (respondents who indicated that they had used pesticides in the past 12 months, or plan to use pesticides sometime during the next 12 months) were recruited to participate further in the pesticide use phase. The participants selected for continued participation kept use diaries that households maintained during the study period. The participating households recorded the application date, product applied, site(s) treated, and application method/equipment used for each pesticide use event. Together with the statistical weights obtained from the screener survey, the pesticide use data from these monthly diaries was used to estimate the percent of households that apply a particular pesticide to a specific site. The collection of pesticide application dates also enables assessing co-occurrence use of across sites and/or products. Another key element of the survey is that it provides household inventory information and provides information regarding the products on hand at the beginning and at the end of the survey period. This information, together with the disposal of old products and purchases of new products, may be used to estimate an average amount of pesticide (active ingredient) applied per event.

Approximately 6,102 households participated in the pesticide use collection phase at the start of the survey period. The number of households participating fell to about 4,214 households in August. According to the REJV, about 1,000 households submitted pesticide use diaries for the entire 12 month period.

As previously stated, the purpose of this memo is to review and evaluate the Valent permethrin submission with respect to EPA and OPP guidelines and standard operating procedures for submission of probabilistic assessments. OPP has recently completed a risk assessment of permethrin using its standard methodologies and procedures (i.e., DEEM-FCID analysis of

exposures through food and SOP calculations using standard inputs for residential exposures) as part of the Phase IV risk assessment.

Where appropriate, this review will also compare and comment upon the inputs and outputs of the Valent submission with those used by OPP in developing OPP's risk assessment document. While this review does not directly compare in significant detail the inputs of the OPP assessment to the selected inputs to the CARES submission, HED has compared the CARES exposures estimates/results with those produced by the Agency using DEEM/FCID (for the food portion of the CARES assessment) and OPP Residential SOPs (for the residential portion of the CARES assessment) and finds the two sets of results to be reasonably comparable.[2] The assessment does not currently reflect the revised drinking water memo completed by the Environmental Fate and Effects Division (EFED) on January 17, 2006 (J. Melendez).

B. CARES Dietary Assessment

The dietary (food only) portion of the CARES permethrin submission was conducted for two age groups – Children 1-2 y.o. and adults 20-49. Consumption data available in CARES reflect the 1994-96/1998 USDA Continuing Survey of Food Intakes by Individuals (CSFII) while pesticide residue data were primarily obtained from the USDA PDP program. Residue values were adjusted by the percent of crop treated in accordance with OPP's SOP 99.6 which indicates the classification of foods with respect to level or degree of blending and indicates the appropriate technique by which percent crop treated is incorporated into a probabilistic assessment. A listing of the commodities used in the Valent permethrin assessment, the source of the data (e.g., PDP data), the percent of the crop which was assumed to be treated, and the processing factors used in the assessment are shown in Table 1 (from S. Ary, *Permethrin. Second Revised Acute, Chronic, and Cancer Dietary Exposure Assessments for the Reregistration Eligibility Decision (RED) Document*; DP Barcode: D325429; February 1, 2006). The dietary values and factors used in the submitted CARES assessment agree with and are identical to those that were used by OPP in its most recent dietary assessement.

Table 1. Commodities, Data Sources, Number of Detects and Percent Crop Treated Used in Valent's and EPA's Dietary Exposure Assessment.

RAC	Valent CARES Assessment			EPA Assessment (S. Ary, D325429, 2/1/06)		
	Data Source	Detects / No. of Samples	% CT Avg./ % CT Max.	Data Source	Detects / No. of Samples	% CT Avg./ % CT Max.
Almond Almond, babyfood oil oil, babyfood	Tolerance	N/A	20/30	Tolerance and field trial data (MRID 43938801)	18/31	20/30
Amaranth, leafy	Translated from spinach PDP data	364/736 223/363	No data	Translated from spinach PDP data	364/736 223/363	No data
Apple, fruit with peel peeled fruit peeled fruit, babyfood dried dried, babyfood	PDP	0/556 0/736 0/184	5/5	PDP	0/556 0/736 0/184	5/5
Apple, juice juice, babyfood	PDP	0/729	5/5	PDP	0/729	5/5
Apple, sauce sauce, babyfood	PDP	0/358	5/5	PDP	0/358	5/5
Artichoke, globe	Tolerance	N/A	30/65	Tolerance and HAFT[5] (MRID 92142063)	N/A	30/60
Arugula	Translated from spinach PDP data	364/736 223/363	No data	Translated from spinach PDP data	364/736 223/363	No data
Asparagus	PDP	1/351 0/708	10/15	PDP	1/351 0/708	15/20
Avocado	Tolerance	N/A	5/5	Tolerance and field trial data (MRID 44229501)	8/8	5/10
Balsam pear	Translated from cucumber PDP data	1/739 1/183	No data	Translated from cucumber PDP data	1/739 1/183	No data
Beef, meat meat, babyfood meat, dried	Tolerance; PDP	0/310 0/309	No data	Tolerance; PDP	0/310 0/309	No data
Beef, meat byproducts meat byproducts, babyfood	Tolerance; feeding and dermal studies	N/A	No data	Tolerance; feeding and dermal studies, see Tables 2 and 3	N/A	No data
Beef, fat fat, babyfood	Tolerance; PDP	0/301 0/291	No data	Tolerance; PDP	0/301 0/291	No data
Broccoli Broccoli, babyfood Chinese	PDP	5/737	15/25	PDP	5/737	15/30

		9/720			9/720	
Brussels sprouts	Translated from head lettuce PDP data	14/329 16/607 1/106	No data	Translated from head lettuce PDP data	16/382	50/50
Cabbage Cabbage, Chinese, napa (tight headed varieties)	Translated from head lettuce PDP data	n14/329 16/607 1/106	20/25	Translated from head lettuce PDP data	16/382	15/20
Cantaloupe	PDP	0/186	10/20	PDP	0/186	10/20
Cardoon	Translated from celery PDP data	N/A	No data	Translated from celery PDP data	150/737 199/736	No data
Casaba	Translated from cantaloupe PDP data	0/186	No data	Translated from cantaloupe PDP data	0/186	No data
Cauliflower	Translated from broccoli PDP data	5/737 9/720	20/40	Translated from broccoli PDP data	5/737 9/720	15/25
Celery Celery, babyfood juice	PDP	150/737 199/736	80/90	PDP	150/737 199/736	65/85
Celtuce	Tolerance	N/A	No data	Translated from celery PDP data	150/737 199/736	No data
Chayote, fruit	Translated from cucumber PDP data	1/739 1/183	No data	Translated from cucumber PDP data	1/739 1/183	No data
Cherry Cherry, babyfood juice juice, babyfood	Tolerance	N/A	10/20	Tolerance and field trial data (MRID 44135001)	25/25	10/20
Chicken, meat meat, babyfood	Tolerance; PDP	0/154 0/145	No data	Tolerance; PDP	0/154 0/145	No data
Chicken, meat byproducts meat byproducts, babyfood	Tolerance; feeding and dermal studies	N/A	No data	Tolerance; feeding and dermal studies, see Tables 2 and 3	N/A	No data
Chicken, fat fat, babyfood	Tolerance; PDP	0/155 0/476	No data	Tolerance; PDP	0/155 0/476	No data
Chinese waxgourd	Translated from cucumber PDP data	1/739 1/183	No data	Translated from cucumber PDP data	1/739 1/183	No data
Chrysanthemum, garland	Translated from spinach PDP data	364/736 223/363	No data	Translated from spinach PDP data	364/736 223/363	No data

Collard	Translated from spinach PDP data	364/736 223/363	5/5	Translated from spinach PDP data	364/736 223/363	5/5
Corn, field, flour flour, babyfood	Tolerance	N/A	1/5	Tolerance and field trial data (MRID 00265258)	5/12	1/5
Corn, field, meal meal, babyfood	Tolerance	N/A	1/5	Tolerance and field trial data (MRID 00265258)	5/12	1/5
Corn, field, bran	Tolerance	N/A	1/5	Tolerance and field trial data (MRID 00265258)	5/12	1/5
Corn, field, starch starch, babyfood	Tolerance	N/A	1/5	Tolerance and field trial data (MRID 00265258)	5/12	1/5
Corn, field, syrup syrup, babyfood	PDP	0/156	1/5	PDP	0/156	1/5
Corn, field, oil oil, babyfood	Tolerance	N/A	1/5	Tolerance and field trial data (MRID 00265258)	5/12	1/5
Corn, pop	Tolerance	N/A	25/35	Tolerance and field trial data (MRID 00265258)	5/12	1/5
Corn, sweet sweet, babyfood	PDP	0/547 0/727 0/181	25/35	PDP	0/547 0/727 0/181	15/30
Crabapple	Translated from apple PDP data	0/556 0/736 0/184	No data	Translated from apple PDP data	0/556 0/736 0/184	No data
Cress, garden upland	Translated from spinach PDP data	364/736 223/363	No data	Translated from spinach PDP data	364/736 223/363	No data
Cucumber	PDP	1/739 1/183	5/10	PDP	1/739 1/183	10/15
Dandelion, leaves	Translated from spinach PDP data	364/736 223/363	No data	Translated from spinach PDP data	364/736 223/363	No data
Egg, whole whole, babyfood white white (solids), babyfood yolk yolk, babyfood	Tolerance; feeding and dermal studies	N/A	No data	Tolerance; feeding and dermal studies	N/A	97.5/97.5
Eggplant	Tolerance	N/A	5/5	Translated from Tomato PDP data	12/742	5/5

Endive	Translated from spinach PDP data	364/736 223/363	No data	Translated from spinach PDP data	364/736 223/363	No data
Fennel, Florence	Tolerance	N/A	No data	Translated from celery PDP data	150/737 199/736	No data
Filbert Filbert, oil	Tolerance	N/A	5/10	Tolerance and field trial data (MRID 92142073)	0/6	5/10
Garlic Garlic, dried dried, babyfood	Tolerance	N/A	20/20	Tolerance and translated from onion PDP data	0/525 0/543	15/20
Goat, meat	Tolerance; Translated from cattle PDP data	0/310 0/309	No data	Tolerance; Translated from cattle PDP data	0/310 0/309	No data
Goat, meat byproducts	Tolerance; feeding and dermal studies	N/A	No data	Tolerance; feeding and dermal studies	N/A	No data
Goat, fat	Tolerance; Translated from cattle PDP data	0/301 0/291	No data	Tolerance; Translated from cattle PDP data	0/301 0/291	No data
Honeydew melon	Translated from cantaloupe PDP data	0/186	15/15	Translated from cantaloupe PDP data	0/186	15/15
Horse, meat	Tolerance; Translated from cattle PDP data	0/310 0/309	No data	Tolerance; Translated from cattle PDP data	0/310 0/309	No data
Horseradish	Tolerance	N/A	No data	Tolerance and HAFT (MRID 41565404)	N/A	No data
Lettuce, head	PDP	14/329 16/607 1/160	60/75	PDP	16/382	49/70
Lettuce, leaf	PDP	14/329 16/607 1/160	60/75	PDP	80/622	51/70
Loquat	Translated from apple PDP data	0/556 0/736 0/184	No data	Translated from apple PDP data	0/556 0/736 0/184	No data
Milk, fat fat, babyfood	PDP	0/768 0/727	33/33	PDP	0/768 0/727	33
Mushroom	PDP	19/552 16/728	No data	PDP	19/552 16/728	No data
Onion, dry bulb dry bulb, babyfood dried dried, babyfood	PDP	0/525 0/543	15/20	PDP	0/525 0/543	10/20

Papaya Papaya, babyfood dried juice	Tolerance	N/A	No data	Tolerance and field trial data (MRID 44453101)	4/4	No data
Parsley, leaves	Translated from spinach PDP data	364/736 223/363	No data	Translated from spinach PDP data	364/736 223/363	No data
Peach Peach, babyfood dried dried, babyfood juice juice, babyfood	PDP	14/563 11/529 28/536	25/25	PDP	14/563 11/529 28/536	20/25
Pear Pear, babyfood dried	PDP	0/165	5/10	PDP	0/165	5/10
Pear, juice juice, babyfood	PDP	0/66	5/10	PDP	0/66	5/10
Pepper, bell bell, babyfood bell, dried bell, dried, babyfood	PDP	52/558	10/15	PDP	52/558	5/15
Pistachio	Tolerance	13/14	50/55	Tolerance and field trial data (MRID 41641001)	13/14	50/55
Pork, meat meat, babyfood	Tolerance; feeding and dermal studies	N/A	No data	Tolerance; feeding and dermal studies	N/A	No data
Pork, meat byproducts meat byproducts, babyfood	Tolerance; feeding and dermal studies	N/A	No data	Tolerance; feeding and dermal studies	N/A	No data
Pork, fat fat, byproducts	Tolerance; feeding and dermal studies	N/A	No data	Tolerance; feeding and dermal studies	N/A	No data
Potato, chips flour flour, babyfood tuber with peel tuber with peel, babyfood tuber without peel tuber without peel, babyfood	PDP	0/370 0/733 0/369	10/10	PDP	0/370 0/733 0/369	5/10
Potato, dry dry, babyfood	PDP	0/370 0/733 0/369	10/10	PDP	0/370 0/733 0/369	5/10
Pumpkin Pumpkin, seed	Translated from cantaloupe PDP data	0/186	15/15	Translated from cantaloupe PDP data	0/186	15/20
Quince	Translated from apple PDP data	0/556 0/736	No data	Translated from apple PDP data	0/556 0/736	No data

		0/184			0/184	
Radicchio	Translated from spinach PDP data	364/736	No data	Translated from spinach PDP data	364/736	No data
		223/363			223/363	
Rhubarb	Tolerance	N/A	No data	Translated from celery PDP data	150/737	No data
					199/736	
Sheep, meat meat, babyfood	Tolerance; Translated from cattle PDP data	0/310	No data	Tolerance; Translated from cattle PDP data	0/310	No data
		0/309			0/309	
Sheep, meat byproducts	Tolerance; cattle feeding and dermal studies	N/A	No data	Tolerance; cattle feeding and dermal studies	N/A	No data
Sheep, fat fat, babyfood	Tolerance; Translated from cattle PDP data	0/301	No data	Tolerance; Translated from cattle PDP data	0/301	No data
		0/291			0/291	
Soybean, seed flour flour, babyfood soy milk soy milk, babyfood oil oil, babyfood	PDP	0/570	1/5	PDP	0/570	<1/<2.5
		0/136			0/136	
Spinach (Fresh)	PDP	364/736	65/75	PDP	364/736	34/70
					223/363	
Spinach (Canned) Spinach, babyfood	PDP	223/363	55	PDP	244/371	39/70
Squash, summer summer, babyfood Squash, winter winter, babyfood	Translated from cucumber PDP data	1/739	10/15	Translated from cucumber PDP data	1/739	10/15
		1/183			1/183	
Swiss Chard	Tolaerance	N/A	No data	Translated from celery PDP data	150/737	No data
					199/736	
Tomato Tomato, babyfood dried dried, babyfood juice	PDP	12/742	10/20	PDP	12/742	5/10
Tomato, paste paste, babyfood puree puree, babyfood	PDP	0/369	10/20	PDP	0/369	5/10
Turnip, greens	Translated from spinach PDP data	364/736	10/10	Translated from spinach PDP data	364/736	10/10
		223/363			223/363	
Turnip, roots	Tolerance	N/A	No data	Tolerance and field trial data (MRID 00261142)	8/8	10/10

Walnut	Tolerance	N/A	No data	Tolerance and field trial data (MRID 92142088)	0/8	5/10
Water, direct, all sources indirect, all sources	EDWCs[4]	N/A	N/A	EDWCs[4]	N/A	N/A
Watermelon Watermelon, juice	Translated from cantaloupe PDP data	0/186	5/15	Translated from cantaloupe PDP data	0/186	10/15

C. Drinking Water Exposure

Residue data generated using the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) was utilized in the Valent CARES submission. The acute and chronic water exposure risk assessment for permethrin was conducted using a 30-year time series of daily Estimated Drinking Water Concentrations (EDWCs) generated by the PRZM/EXAMS Platform (Pe4vo2.Pl), and using the State of Maine, Potato Index Reservoir standard scenario (MepotatoC). The permethrin specific input parameters were those used for the Maine potato scenario in EPA Memorandum (July 16, 2004): Tier II Estimated Drinking Waer Concentrations of Permethrin (D298743). The Maine potato scenario does not currently reflect the recommended scenario selected in the revised drinking water memo completed by the Environmental Fate and Effects Division (EFED) on January 17, 2006 (J. Melendez). The 2006 revised memo examined the Georgia onion scenario because it was deemed to be more realistic (regarding use rate and number of applications per year) based on comments received by the Agency during Phase 3 of the permethrin public process.

D. Residential Exposures

The residential portion of the assessment relied extensively upon the data from the Residential Exposure Joint Venture (REJV) survey. Based on the information collected under the REJV and the scenarios used in HED's permethrin risk assessment, the Valent CARES assessment included 18 residential uses (including LCO/PCO applications) for carbaryl in its assessment: 4 uses for lawn care, 1 use for vegetable garden care, 1 use for outdoor wasp and hornet control, 3 uses for indoor crack and crevice treatments, 1 use for termite treatments, 2 uses for pet care, 2 fogger uses (indoor and outdoor), 1 use for indoor flying insect knockdown aerosols, 1 use for impregnated clothing, 1 use for indoor carpet aerosols, and 1 use for public health mosquito control. Table 2 lists these 15 residential uses and the corresponding exposure scenarios (applicator, post-application). HED has verified that these scenarios are of most interest with respect to high-end exposures and most relevant for inclusion in the residential portion of an aggregate probabilistic risk assessment.

Table 2. Residential Scenarios Used in Valent Permethrin CARES Submission

Scenario	Products/Uses	Pathway	Route	Receptor
Lawn Care (Broadcast)	Concentrates/Handwand/Pump sprayer - both LCO and homeowner applied Granular/Pellets (push spreader) - both LCO and homeowner applied	During Application	Dermal	Adult

			Inhalation	Adult
		Post Application	Dermal	Adult, Child
			Ingestion	Child
Vegetable Garden Care	Granular/Dust/Powder (shaker can)	During Application	Dermal	Adult
			Inhalation	Adult
		Post Application	Dermal	Adult
Outdoor Wasp and Hornet	Aerosol	During Application	Dermal	Adult
			Inhalation	Adult
Indoor Crack & Crevice	Aerosol Concentrates/Handwand/Pump sprayer - both LCO and homeowner applied	During Application	Dermal	Adult
			Inhalation	Adult
		Post Application	Dermal	Adult, Child
			Ingestion	Child
Termite Treatment	Liquid Perimeter Treatment (PCO applied)	Post Application	Inhalation	Adult, Child
Pet Care	RTU Spot-on (no applicator exposure assumed for Spot-on treatments) RTU Shampoo	During Application	Dermal	Adult
			Inhalation	Adult
		Post Application	Dermal	Adult, Child
			Ingestion	Child
Outdoor Fogger	Aerosol Fogger	Post Application	Inhalation	Adult, Child
Indoor Fogger	Aerosol Fogger	During Application	Dermal	Adult
			Inhalation	Adult
		Post Application	Dermal	Adult, Child
			Ingestion	Child
Indoor FIK	Aerosol	During Application	Dermal	Adult
			Inhalation	Adult

		Post Application	Inhalation	Adult, Child
Impregnated Clothing	Clothing	Post Application	Dermal	Adult, Child
			Ingestion	Child
Indoor Carpet & Room	Aerosol	During Application	Dermal	Adult
			Inhalation	Adult
		Post Application	Dermal	Adult, Child
			Ingestion	Child
Public Health - Mosquitos	Ultra Low Volume Fogger	Post Application	Inhalation	Adult, Child

Various inputs extracted from the REJV database were used in Valent's CARES submission. The REJV data represent an empirically-based, statistically representative profile of temporal (across a complete 12 month period) permethrin product use in U.S. households. The profiles of consumer product use (with the exception of impregnated clothing) reported by participating households includes specific information regarding date, method, and site of application. The participating household use profiles also provide co-occurrence of product applications (e.g., application of the same or different products containing permethrin to one or more sites on a given calendar day). It is important to note that the REJV survey data used in the Valent CARES submission were not statistically weighted. Statistical weights (for each of the participating REJV survey households) have been developed in collaboration with EPA's Office of Pesticide Programs (OPP) based on demographic criteria from the U.S. Census that includes geographic region, household income, household size, age of head of household, and household metropolitan statistical area size.

The REJV survey was designed to address aggregate exposure from co-occurrent uses. This issue is especially important to account for application and postapplication exposures resulting from treating or being exposed to (in the case of postapplication exposures) multiple sites (i.e., lawn and garden; pet and indoor carpet) during the same day (event). The CARES developers anticipate incorporating the REJV into future versions of the software. Currently, CARES requires input of various pesticide use statistics (from the REJV data or other data source) which its Event Generator uses to simulate pesticide use profiles. The pesticide use statistics required for input in the CARES software include: the percent of households applying the product, a co-occurrence matrix containing conditional probabilities of use, the number of applications, distribution of use by season and day of week. The CARES Event Generator was designed to incorporate these inputs and simulate pesticide use profiles as reported by REJV respondents.

The Valent permethrin CARES assessment captured co-occurrence in a site-level co-occurrence matrix. This site-level matrix contains the conditional probabilities of treating multiple sites on the same day (event). These statistics are not constructed at the product-formulation level. Permethrin users have many different product-formulations (dust, granular, ready-to-use, liquid) from which to treat various sites. And, according to the REJV, permethrin users that treat

multiple sites on a given day often used the same product-application methods to treat all sites (e.g., mix and apply a liquid concentrate using a handwand sprayer to lawns and ornamental plants on the same day). Using the site-level co-occurrence matrix leads to simulated use patterns in which users apply different permethrin products to treat different sites, which is an event infrequently observed in the REJV data. Capturing co-occurrence at the scenario level (product-site-application method) would more accurately capture those use patterns. The effect of accounting for co-occurrence increases when exposure varies across product formulations and when exposure becomes a concern when a large amount of pesticide (area treated or multiple sites) is mixed and applied.

In addition to identifying the most common residential uses of permethrin for inclusion in the permethrin CARES assessment, the REJV survey data was also used to assign a probability of treatment to each use scenario (e.g., broadcast application to lawn) and, subsequently, a "market share" for each product type within a scenario (e.g., granular/pellet use via spreader within the broadcast application to lawn scenario). These "market shares" are based on the reported incidence of each product type/application method within a specific scenario (site of application) within the permethrin subset of the REJV database.

The REJV database was also used to assign month-of-year and day-of-week scenario probabilities. That is, the probability or likelihood that permethrin would be applied during any given month during a one year period and on any given day of the week was derived and incorporated into the assessment. In addition, the REJV survey results were used to derive as inputs to the probabilistic model the treatment intervals (i.e., the time period between subsequent applications; permethrin treatment intervals range from 7 days to 30 days); the frequency of permethrin applications per year; and the co-occurrence probabilities. This latter information was used to determine the frequency with which two or more scenarios (and associated product uses) would co-occur during a toxicologically-relevant time window (here, for permethrin, 24 hours).

Finally, base information such as application rates, area treated, transfer coefficients, frequency of hand-to-mouth contact etc. is also presented in the CARES document. These values are generally derived from either the EPA's Organophosphate Cumulative Risk Assessment (EPA 2002) or the Permethrin RED. The specific information is present in the Valent submission and is not repeated here.

E. CARES Results

Dietary per Capita Exposure Results

Valent reported dietary exposures (on a mg/kg per capita basis) and MOE's corresponding to the 99.9 percentile for both children 1-2 and adults 20-49. For children 1-2 years old, Valent reported exposures at the 99.9th percentile of 0.0269 mg/kg (equivalent to an MOE of 929). For adults 20-49, Valent reported exposures at the 99.9th percentile of 0.0107 mg/kg (equivalent to an MOE of 2332). These results are in reasonable agreement with those generated by HED using its DEEM program.

Drinking Water per Capita Exposure Results

Valent reported drinking water exposures (on a mg/kg per capita basis) and MOE's corresponding to the 99.9 percentile for both children 1-2 and adults 20-49. For children 1-2 years old, Valent reported exposures at the 99.9th percentile of 0.000749 mg/kg (equivalent to an MOE of 33391). For adults 20-49, Valent reported exposures at the 99.9th percentile of 0.000447 mg/kg (equivalent to an MOE of 55932). Again, these results do not reflect the results presented in the revised drinking water memo completed by the Environmental Fate and Effects Division (EFED) on January 17, 2006 (J. Melendez). HED believes that the differences between the Maine potato and Georgia onion drinking water exposure scenarios are negligible with respect to changing the aggregate risk picture and, in fact, the Maine potato scenario resulted in higher exposure numbers so it can be considered conservative for use in the Valent CARES submission.

Residential per Capita Exposure Results
Valent reported residential exposures (on a mg/kg per capita basis) and MOE's corresponding to the 99.9th percentile for both children 1-2 and adults 20-49. For children 1-2 years old, Valent reported exposures at the 99.9th percentile of 0.801 mg/kg (equivalent to an MOE of 624). For adults 20-49, Valent reported exposures at the 99.9th percentile of 0.337 mg/kg (equivalent to an MOE of 1484). These estimates are expressed on *per capita* basis, i.e., all individuals (or all exposure-days) are considered and not just those individuals (or exposure days) on which an actual application occurs. This is a fundamental difference between the residential assessment calculations performed by HED in its assessment (as per the Residential SOPs) and those performed in the Valent CARES submission: the residential exposure estimates calculated by the Agency reflect exposure estimates to a user on the day of application whereas those represented by Valent apply to all individuals – users or not – on all days – whether permethrin was used or not. The two methods of expressing risk cannot be considered directly comparable, but should rather be seen as two alternate ways in which exposures can be viewed.

Overall per Capita Aggregate Exposure Results
Valent reported aggregate MOEs corresponding to the 99.9th percentile for both children 1-2 and adults 20-49. For children 1-2 years old, Valent reported an aggregate MOE at the 99.9th percentile of 433. For adults 20-49, Valent reported an aggregate MOE at the 99.9th percentile of 915. These aggregate results are in reasonable agreement with those generated by HED in the permethrin risk assessment.

F. Conclusions

In reviewing the Valent permethrin CARES submission, HED focused on the residential exposure aspect for a variety of reasons:

1) residential exposure was the driver in HED's deterministic aggregate non-cancer assessment;
2) the acute food and water aggregate MOE was greater than 200,000 in HED's deterministic aggregate non-cancer assessment; and
3) the Maine potato water run used in the Valent submission does not reflect the current use of the Georgia onion water run in the revised drinking water memo completed by EFED on January 17, 2006 (J. Melendez).

On the whole HED believes the Valent CARES assessment provides valuable complementary information to HED regarding aggregate exposure to permethrin. The results generated in the permethrin CARES assessment are generally in reasonable agreement with those generated by HED in the current permethrin risk assessment (Smith 3/14/06). In the current risk assessment, HED has concluded that combined residues of permethrin from food, drinking water, and other potential residential exposures do not result in short-term aggregate risks of concern to population subgroups. The Valent permethrin CARES assessment allows HED to provide support and better characterization to HED's deterministic aggregate non-cancer assessment (developed from standard operating procedures for estimating aggregate exposure).

[1] The Valent assessment assumed that households were exposed to both "self-applied" pesticides (i.e., products that were for purchase and use by residential users) and "professional-applied" pesticides (i.e., products that are applied by pest control operators (PCOs) or lawn care operators (LCOs).

[2] As discussed in additional detail later in this document, HED's standard SOP's for residential exposure calculate exposures on a per user basis while CARES residential exposures are expressed over all individuals (i.e., on a per capita basis). These results, thus, are not directly comparable. For example, estimated CARES residential exposures at the 99 or 99.9 percentile(on a per capita basis) can not be directly compared to those "high end" exposure developed from HED's SOPs for residential exposures (on a per user basis).